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NOTICE OF ALLOWANCE AND FEE(S) DUE

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09/15/2009

HOXIE & ASSOCIATES LLC 75 MAIN STREET, SUITE 301 MILLBURN, NJ 07041 EXAMINER

SHTERENGARTS, SAMANTHA L

ART UNIT PAPER NUMBER

1626

DATE MAILED: 09/15/2009

APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/586,420	07/19/2006	Maurice Van Eis	NOV-05-US	4844	

TITLE OF INVENTION: INDOLYLMALEIMIDE DERIVATIVES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	12/15/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or <u>Fax</u> (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where

appropriate. All further indicated unless correct maintenance fee notification	ed below or directed oth	ng the Patent, advance of nerwise in Block 1, by (a	rders and notification a) specifying a new co	of m orres	naintenance fees w pondence address;	/ill be and/or	mailed to the current (b) indicating a sepa	corresponder rate "FEE A	ice address as DDRESS" for
	ock 1 for any change of address)]	Note: A certificate of mailing can only be used for domestic mailings Fee(s) Transmittal. This certificate cannot be used for any other accompa papers. Each additional paper, such as an assignment or formal drawing have its own certificate of mailing or transmission.				accompanying		
50446 HOXIE & ASS 75 MAIN STRE MILLBURN, N	72009			Certificate of Mailing or Transmission I hereby certify that this Fee(s) Transmital is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.					
								C.	Depositor's name)
									(Signature)
									(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENT	ГOR		ATTO	RNEY DOCKET NO.	CONFIRMA	ATION NO.
10/586,420 TITLE OF INVENTION	07/19/2006 i: INDOLYLMALEIMII	DE DERIVATIVES	Maurice Van Eis				NOV-05-US	48	44
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE D	UE	PREV. PAID ISSUI	E FEE	TOTAL FEE(S) DUE	DAT	TE DUE
nonprovisional	NO	\$1510	\$300		\$0		\$1810	12/15/2009	15/2009
EXAM	IINER	ART UNIT	CLASS-SUBCLASS	ss					
SHTERENGART	S, SAMANTHA L	1626	514-253010	_	l				
CFR 1.363). Change of corresp Address form PTO/S. "Fee Address" ind PTO/SB/47; Rev 03-(Number is required. 3. ASSIGNEE NAME A PLEASE NOTE: Un	ND RESIDENCE DATA less an assignee is ident h in 37 CFR 3.11. Comp	inge of Correspondence	data will appear on th	p to nativ ingle or a attor l be p r typ ne pa	3 registered patentely, efirm (having as a gent) and the namency or agents. If printed. e) tent. If an assignassignment.	membes of uno nam	er a 2	ocument has	been filed for
		categories (will not be pr	<u> </u>						
4a. The following fee(s) Issue Fee Publication Fee (N Advance Order -	permitted)	 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) A check is enclosed. Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number (enclose an extra copy of this form). 							
5. Change in Entity Sta	tus (from status indicated s SMALL ENTITY state		☐ h. Applicant is no	lone	ver claiming SMAI	LEN	TITY status. See 37 CF	FR 1 27(g)(2)	
NOTE: The Issue Fee an	d Publication Fee (if req	uired) will not be accepte	d from anyone other th						
interest as snown by the	records of the United Sta	ites Patent and Trademark	Comce.						
Authorized Signature					Date				
Typed or printed name			Registration No						
an application. Confiden	tiality is governed by 35 dapplication form to the ions for reducing this bu. Virginia 22313-1450. DC	ER 1.311. The informatic U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to th O NOT SEND FEES OR	1.14. This collection is depending upon the in	s esti ndivi	imated to take 12 r idual case. Anv co	ninutes mment	to complete, includin s on the amount of tir	g gathering, _I ne vou requir	preparing, and re to complete

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

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10/586,420 07/19/2006		Maurice Van Eis	NOV-05-US	4844		
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HOXIE & ASSO	CIATES LLC	SHTERENGARTS, SAMANTHA L				
75 MAIN STREET			ART UNIT	PAPER NUMBER		
MILLBURN, NJ 0	7/041		1626			
			DATE MAILED: 09/15/2009			

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 281 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 281 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)					
	10/586,420	VAN EIS ET AL.					
Notice of Allowability	Examiner	Art Unit					
	Samantha L. Shterengarts	1626					
The MAILING DATE of this communication appear All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIOF of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in this ap or other appropriate communicatio IGHTS. This application is subject	oplication. If not included n will be mailed in due course. THIS					
1. X This communication is responsive to <u>amendments filed 18</u>	<u>May 2009</u> .						
2. The allowed claim(s) is/are 1-4 and 8-10 (renumbered 1-7)	,						
 3. Acknowledgment is made of a claim for foreign priority ur a) All b) Some* c) None of the: 1. Certified copies of the priority documents have 							
□ Certified copies of the priority documents have							
3. ☐ Copies of the certified copies of the priority do	• • • • • • • • • • • • • • • • • • • •						
International Bureau (PCT Rule 17.2(a)).		manona, cago application from the					
* Certified copies not received:							
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.							
	4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.						
5. CORRECTED DRAWINGS (as "replacement sheets") mus	st be submitted.						
(a) ☐ including changes required by the Notice of Draftspers	on's Patent Drawing Review (PTO	-948) attached					
1) ☐ hereto or 2) ☐ to Paper No./Mail Date							
(b) ☐ including changes required by the attached Examiner's Paper No./Mail Date	s Amendment / Comment or in the	Office action of					
Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in t							
6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.							
Attachment(s) 1. ☐ Notice of References Cited (PTO-892)	5. ☐ Notice of Informal I	Datant Application					
 Induce of References Cited (PTO-092) Induce of References Cited (PTO-	6. ☐ Interview Summary	• •					
	Paper No./Mail Da	ate					
3. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 4/6/09, 7/19/06	7. 🛛 Examiner's Amend	ment/Comment					
Examiner's Comment Regarding Requirement for Deposit of Biological Material	8. 🛛 Examiner's Statem	ent of Reasons for Allowance					
-	9. Other						

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DETAILED ACTION

1. Claims 1-4 and 7-10 are currently pending in the instant application.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Richard Elder on August 26, 2009.

In the Claims:

Claim 7: CANCELLED.

Claim 10: DELETE claim 10 and REPLACE with the following:

10. A method for treating disorders or diseases mediated by T lymphocytes and/or PKC, in a subject in need of such treatment, wherein the disease or disorder is selected from the group consisting of acute or chronic rejection of organ or tissue allo- or xenografts, graft versus host diseases, T-cell mediated acute or chronic inflammatory diseases or disorders, autoimmune diseases, rheumatoid arthritis, osteoarthritis, systemic lupus erythematosus, Hashimoto's thyroiditis, multiple sclerosis, myasthenia gravis, diabetes type I or II, respiratory diseases, inflammatory liver injury, inflammatory glomerular injury, cutaneous manifestations of immunologically mediated disorders or illnesses, inflammatory and hyperproliferative skin diseases, inflammatory eye diseases, inflammatory bowel disease, Crohn's disease, and

ulcerative colitis, which method comprises administering to said subject an effective amount of a compound according to claim 1, or a pharmaceutically acceptable salt thereof.

REASONS FOR ALLOWANCE

3. The following is an examiner's statement of reasons for allowance: The instantly claimed compounds are novel and non-obvious over the prior art because of the R group. The closest prior art is U.S. Patent no. 7,220,774, Albert et al. This reference does not encompass the scope of the instant application, which includes the aforementioned novelty. This reference lacks identical or obvious substituents at the aforementioned positions. A person of ordinary skill in the art would not have expected that making these structural modifications would retain identical activity as disclosed in the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

- 4. Claims 1-4 and 8-10 (renumbered 1-7) are allowed.
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samantha Shterengarts whose telephone number is (571)270-5316. The examiner can normally be reached on Monday thru Thursday 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samantha L. Shterengarts/ Examiner, Art Unit 1626 /Kamal A Saeed/ Primary Examiner, Art Unit 1626